Trace Elements

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Trace Elements Standard of Practice 1 (TE S1): Method Detection Limit Calculation Initial validation of each trace element for each biological matrix must include calculation of the method detection limit (LOD) using a published protocol and must be based on results that includes an appropriate matrix blank or base level.	Calculation of the method LOD may be based on the ISO/IUPAC harmonized protocol of three (3) standard deviations (n≥ six (6)); or on the EPA procedure for environmental targets and 3.143 standard deviations (n≥ seven (7)); or another published procedure. If a matrix blank is unavailable, such as for essential nutrient elements, an alternative approach can be used (e.g., use of a low-level QC, matrix-matched calibration standard, reagent blank, etc.).
Trace Element Standard of Practice 2 (TE S2): Materials Contamination Control The laboratory must implement procedures to ensure that materials distributed for specimen collection and supplies used for processing in the laboratory are free from significant contamination for each element tested.	To ensure that tubes or containers are free from contamination for each element tested, specimen collection tubes may be lot-tested and certified as free from significant trace element contamination, or manufacturer-certified for trace element use. Where appropriate, laboratory supplies (e.g., flasks, autosampler tubes, and pipet tips), used for trace element analysis may need to be pre-checked for contamination and/or acid-washed (e.g., with dilute nitric acid), and certified as fit for purpose. Disposable plastic ware can be verified as contamination-free by randomly checking materials by lot number. Monitoring of reagent blank data is appropriate to documenting contamination of the system (e.g., pipette tips and autosampler sample cups).

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Trace Element Standard of Practice 3 (TE S3): Processing Contamination Control To minimize contamination errors during trace element analysis: a) work must be performed in a dedicated clean area; and b) specimen aliquots must be protected from dust contamination before and during analysis.	a) Clean area refers to space that is dedicated to testing for trace elements, and is regularly cleaned by wet wiping flat surfaces. b) If an ISO 5 (a.k.a. Class 100) clean room is unavailable, specimen aliquots should be protected by use of dust protection devices (e.g., furnace AAS carousels containing unanalyzed samples should be protected with dust covers before and during analysis; ICP-MS autosamplers should be protected from airborne contamination.)
Trace Elements Standard of Practice 4 (TE S4): Order of Testing If venous blood specimens are collected for multiple analyses including trace element testing, a volume sufficient for the initial trace element test and any repeat analysis must be transferred to a tube or container that is certified as free from significant trace element contamination trace element-free tube under clean conditions before any other processing or testing of the specimen.	Implementing this protocol may minimize inadvertent specimen contamination from other clinical testing areas. As an alternative, the testing for trace elements may be completed prior to other clinical testing.
Trace Elements Standard of Practice 5 (TE S5): Calibration Protocols On each day of testing, the laboratory must run a calibration curve that: a) includes a blank and at least three (3) calibration standards;	

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b) is matrix matched to the specimens being tested, unless validation studies indicate the absence of matrix effects; and c) is re-calibrated at least every eight (8) hours of testing, unless longer instrument stability is validated, but not longer than twenty-four (24) hours.	b) Dilution of a specimen prior to analysis may not eliminate matrix effect. Validation studies must be performed to verify that there is no change in the slope of the calibration curve if aqueous standards are used. c) Less stable instruments or methods may require more frequent calibration.
Trace Elements Standard of Practice 6 (TE S6): Quality Control The laboratory must: a) ensure that at least two (2) levels of quality control (QC) are included in each test run for all non-essential toxic elements, e.g., normal and abnormal-high concentration; b) ensure three (3) levels of QC for the essential trace elements, QC must include low (if available), intermediate and elevated that covers the analytical range of values reported; c) use matrix-matched QC materials; d) run at least one (1) level of QC at the end of each batch of specimens; and e) adjust the frequency of instrument re-calibration based on quality control data.	b) For the limited purposes of TE S6b, the definition of "essential" applies only to copper (Cu), zinc (Zn) and selenium (Se) in blood, serum or plasma, and to iodine (I) in urine. d) An analytical batch is the maximum number of samples that can be run with an autosampler (ICP-MS) or carousel tray (GFAAS).

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Trace Elements Standard of Practice 7 (TE S7): Unacceptable Specimens In addition to the requirements in Specimen Processing Standard of Practice 4, whole blood specimens with visible clots, or urine specimens with visible blood or fecal materials, must be rejected as unsatisfactory for analysis.	
Trace Elements Standard of Practice 8 (TE S8): Repeat Analysis All trace element results that are above the laboratory's definition of elevated (or below the definition of low) must be verified by repeat analysis. The laboratory must: a) define trace element concentrations for elevated and, where appropriate, low; b) define critical call values for trace elements where appropriate; c) establish reportable protocols for lead, cadmium, mercury and arsenic consistent with the requirements of 10NYCRR Parts 22.6 and 22.7 (NYS Heavy Metals Registry) and report results, as applicable, according to Public Health Reporting Standard of Practice 1; d) establish criteria for the maximum discrepancy allowable on duplicate measurements that are consistent with the expected method repeatability; and e) perform a third analysis (triplicate) when the discrepancy between the first two (2) results exceeds	A new aliquot from the original specimen should be used when a repeat analysis is performed. A clinical action threshold is defined as that level where clinical intervention would be recommended. Where no action threshold has been established (e.g., biomonitoring studies), the laboratory may define elevated based on published or laboratory derived data. Repeat analysis is not normally required for values that fall within the reference range. The laboratory must define elevated (or low) for repeat analysis purposes, while recognizing that these may not always be equivalent to the upper (or lower) limit of the reference interval.

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the maximum allowed in (c) above.	
Trace Elements Standard of Practice 9 (TE S9): Reporting Potential Contamination In addition to the requirements in Reporting Standard of Practice 2, when a specimen is received in a collection tube or container that is not certified for trace elements, the report must state that a non-certified trace element specimen collection tube was used and might produce a falsely elevated result.	When a specimen is received in a collection tube that is either not pre-certified by the testing laboratory or not certified by the manufacturer for trace elements, the test result can be reported without comment when the result is within the reference range.